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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/684,109	10/10/2003	Peter J. DeVries	6989.US.02	5090
23492	7590	11/01/2007		
ROBERT DEBERARDINE ABBOTT LABORATORIES 100 ABBOTT PARK ROAD DEPT. 377/AP6A ABBOTT PARK, IL 60064-6008			EXAMINER XIE, XIAOZHEN	
			ART UNIT 1646	PAPER NUMBER
			NOTIFICATION DATE 11/01/2007	DELIVERY MODE ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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**Office Action Summary**

Application No.

10/684,109

Applicant(s)

DEVRIES ET AL.

Examiner

Xiaozhen Xie

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 07 August 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 5-8, 11, 12, 14-36, 38-40, 42-45, 47-49 and 55-61 is/are pending in the application.
- 4a) Of the above claim(s) 6-8, 14-35, 38, 39, 42-45, 47 and 48 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 5, 11, 12, 36, 40, 49, 55, 60 and 61 is/are allowed.
- 6) ☒ Claim(s) 56-59 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input checked="" type="checkbox"/> Other: <u>MESH definitions</u> .                 |

## **DETAILED ACTION**

### ***Response to Amendment***

Applicant's amendments of the specification and the claims filed on 7 August 2007 have been entered. Applicant's submission of the Declaration made under the Budapest Treaty by Ms. Dianne Casuto for a biological deposit of a cell line expressing Ab12 is acknowledged.

### ***Election/Restrictions***

Claims 5, 11, 12, 36, 40, 49, 60 and 61 are directed to an allowable product. Pursuant to the procedures set forth in the Official Gazette notice dated March 26, 1996 (1184 O.G. 86), claims 55-59, directed to the process of using the patentable product, previously withdrawn from consideration as a result of a restriction requirement, are now subject to being rejoined. Claims 55-59 are hereby rejoined and fully examined for patentability under 37 CFR 1.104.

Claims 1-4, 9-10, 13, 37, 41, 46 and 50-54 have been cancelled. Claim 61 has been added. Claims 5-8, 11, 12, 14-36, 38-40, 42-45, 47-49 and 55-61 are pending. Claims 6-8, 14-35, 38-39, 42-45, 47, 48 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Claims 5, 11, 12, 36, 40, 49 and 55-61 are under examination.

### ***Claim Rejections Withdrawn***

Art Unit: 1646

The rejection of claims 1-5, 9-11, 49, 52 and 53 under 35 U.S.C. 101, as the claims drawn to non-statutory subject matter, is withdrawn in response to Applicant's cancellation and amendment of the claims to include a limitation wherein the antibody is isolated.

The rejection of claims 1-4, 9, 10, 12, 13, 36, 37, 40, 41, 46, 49-54 and 60 under 35 U.S.C. 112, first paragraph, for lack of enablement, is withdrawn in response to Applicant's cancellation and amendment of the claims to: 1) recite an isolated antibody or antibody fragment thereof comprising both the heavy chain variable region and the light chain variable region set forth in the defined amino acid sequences; and 2) make a deposit of the cell line expressing Ab12 in ATCC, and submitting a Declaration made under the Budapest Treaty by Ms. Dianne Casuto in accordance to the criteria set forth in 37 C.F.R. §§ 1.801-1.809.

The rejection of claim 2, under 35 U.S.C. 112, second paragraph, as being indefinite, is withdrawn in response to Applicant's cancellation of the claim.

The rejection of claim 3-5, 9-13, 36 and 37, under 35 U.S.C. 112, second paragraph, as being indefinite, is withdrawn in response to Applicant's cancellation and amendment of the claims.

The rejection of claim 54, under 35 U.S.C. 112, second paragraph, as being indefinite for reciting the term Ab12 as the sole means of identifying the claimed molecule, is withdrawn in response to Applicant's cancellation of the claim.

The rejection of claims 1, 2, 46, 49-54 and 60 under 35 U.S.C. 102(b) as being anticipated by Elliott et al. (U. S. Patent No: 5,885,574), is withdrawn in

Art Unit: 1646

response to Applicant's cancellation and amendment of the claims to limit the antibody to be Ab12 (ATCC Accession No: PTA-5554).

***New Grounds of Rejections***

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 57 and 58 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for *a method of treating pure red-cell aplasia comprising administering to a mammal afflicted with the disease the antibody or antibody fragment of Ab12 (ATCC Accession No. PTA-5554) to activate the endogenous activity of EpoR*, does not reasonably provide enablement for treating any aplasia. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required, are summarized in *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue." These factors include, but are not limited to: the breadth of the claims, the nature of the invention, the state of the prior art,

Art Unit: 1646

the level of one of ordinary skill, the level of predictability in the art, the amount of direction provided by the inventor, the existence of working examples, and the quantity of experimentation needed to make or use the invention based on the content of the disclosure. See also *Ex parte* Forman, 230 USPQ 546 (BPAI 1986).

The claims are broad in that they read on treating any aplasia. The specification discloses that an agonistic hu-EpoR antibody, Ab12 (ATCC Accession No. PTA-5554), activates the endogenous activity of EpoR *in vitro* (Figures 6, 8, 14 and 31) and increases reticulocyte count and hematocrit in transgenic mice (Figures 32-34). Therefore, the antibody or antibody fragment thereof can be used to treat pure red-cell aplasia and anemia in a mammal suffering from low reticulocyte count. The specification, however, does not provide sufficient support for treating other aplasia. The term "aplasia" generally refers to abnormalities in organs with congenital defects (e.g., defective development or congenital absence of a limb, organ, or other body part) (see MESH definition). These diseases differ in pathology and treatment. The specification fails to provide guidance as to how the artisan could treat all these diseases. Thus, the scope of patent protection sought by Applicant as defined by the claims fails to correlate reasonably with the scope of enabling disclosure set forth in the specification.

Due to the large quantity of experimentation necessary to determine whether the AB12 antibody or antibody fragment thereof can be used to treat any aplasia, the lack of direction/guidance presented in the specification, the absence

Art Unit: 1646

of working examples directed to same, the complex nature of the invention, the state of the prior art which establishes the diversity, complexity and unpredictability of the diseases from different tissue origin, the breadth of the claims, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 56, 58 and 59 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 56, 58 and 59 recite modulating an endogenous activity of a human erythropoietin receptor. The term "modulating" can be interpreted as increasing and decreasing. Claims 55 and 56, and claims 57 and 58 would be identical unless the term "modulating" is interpreted as decreasing. Therefore, the metes and bounds of the limitation cannot be determined.

***Conclusion***

CLAIMS 5, 11, 12, 36, 40, 49, 55, 60 and 61 ARE ALLOWABLE.

CLAIMS 56-59 ARE REJECTED.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.**

Art Unit: 1646

See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

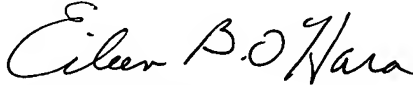
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Xiaozhen Xie whose telephone number is 571-272-5569. The examiner can normally be reached on M-F, 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary B. Nickol, Ph.D. can be reached 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1646

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Xiaozhen Xie, Ph.D.  
October 23, 2007

  
EILEEN B. O'HARA  
PRIMARY EXAMINER